Immunization Update

Amy Herrington, DNP, RN, CEN, CNE

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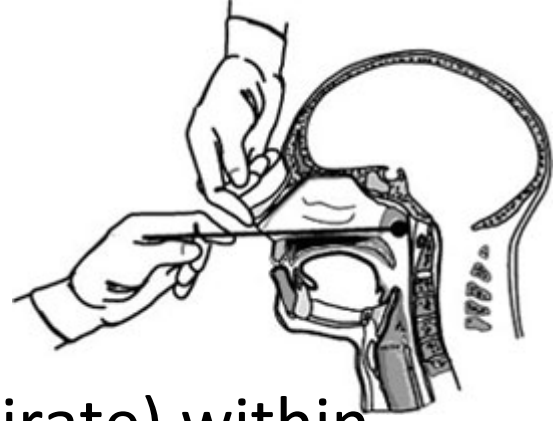
CABINET FOR HEALTH AND FAMILY SERVICES

Bordetella pertussis

- Outbreaks have been reported in several counties
- "The hundred day cough"
  - Three stage illness (catarrhal, paroxysmal, and convalescent) that lasts 4-12 weeks
  - Classic presentation: no fever, coryza, paroxysmal cough, posttussive vomiting, whoop
- Transmitted via respiratory aerosols; highly infectious
- Immunity from both natural disease and vaccination wanes over time
- Affects persons of all ages; infants most vulnerable to severe disease and death

If pertussis is suspected



- Collect an nasopharyngeal (NP) swab for PCR testing (or aspirate) within first 3 weeks of illness.
  - Serology can be useful later in illness but commercial serologic assays have wide variety, are difficult to interpret, and not generally recommended.
- Prescribe antibiotic treatment if <21 days since cough onset.
  - Abx may not lessen symptoms but reduces infectiousness
- Prescribe PEP antibiotics for high-risk close contacts.
  - Household members & infant/pregnant contacts
- Recommend vaccine for those not up-to-date.
- Report to public health.

- Infants and pregnant women are the most vulnerable risk groups.
  - Infants <6 mos are most likely to require hospitalization or die from pertussis.
- Tdap needed during each pregnancy (27-36w gest).
- Tdap in the 3rd trimester prevents 78% of pertussis cases in infants <2 mos.

	Pertussis	Parapertussis
Symptoms	Cough illness lasting 2+ weeks	Cough illness but reduced severity (bacterium does not produce pertussis toxin)
Diagnostics	PCR preferred (within first 3 weeks of illness)	Some PCR assays can distinguish between pertussis and parapertussis
PEP	High risk contacts and household members	Not indicated
Vaccine	DTaP and Tdap	No
Report to public health	Yes	No

RSV

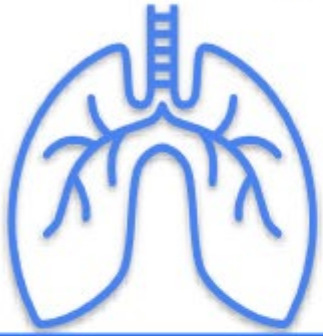
- Respiratory Syncytial Virus (RSV) can cause illness in people of all ages but may be especially serious for infants and older adults.
- Infants and older adults with chronic medical conditions like heart or lung disease, weakened immune systems, or who live in nursing homes or long-term care facilities, are at highest risk of serious illness and complications from RSV.
- Symptoms of RSV infection may include runny nose, decreased appetite, coughing, sneezing, fever, or wheezing.
- Most people recover in a week or two, but RSV can be serious, resulting in shortness of breath and low oxygen levels.
- RSV can also sometimes lead to worsening of other medical conditions such as asthma, chronic obstructive pulmonary disease or congestive heart failure.
- Older adults and infants who get very sick from RSV may need to be hospitalized. Some may even die.

Centers for Disease Control and Prevention (2023*). Respiratory syncytial virus (RSV).* https://www.cdc.gov/vaccines/hcp/vis/vis-statements/rsv.html

RSV

- Vaccination with a single dose of the GSK or Pfizer RSV vaccines demonstrated moderate to high efficacy in preventing symptomatic RSV-associated lower respiratory tract disease (LRTD) over two consecutive RSV seasons among adults aged ≥60 years.
- Although trials were underpowered to estimate efficacy against RSV-associated hospitalization and death, prevention of LRTD, including medically attended LRTD, suggests that vaccination might prevent considerable morbidity from RSV disease among adults aged ≥60 years.
- Although both vaccines were generally well-tolerated with an acceptable safety profile, six cases of inflammatory neurologic events (including GBS, ADEM, and others) were reported after RSV vaccination in clinical trials.
  - Whether these events occurred due to chance, or whether RSV vaccination increases the risk for inflammatory neurologic events is currently unknown. Until additional evidence becomes available from postmarketing surveillance clarifying the existence of any potential risk, RSV vaccination in older adults should be targeted to those who are at highest risk for severe RSV disease and therefore most likely to benefit from vaccination.
  - The recommendation for shared clinical decision-making is intended to allow flexibility for providers and patients to consider individual risk for RSV disease, while taking into account patient preferences.

If shared clinical decision-making is recommended adults who may be at higher risk of RSV disease include persons with:



Chronic lung diseases such as COPD and asthma

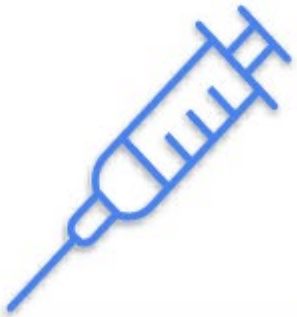
Chronic cardiovascular diseases such as congestive heart failure and coronary artery disease

Immune compromise

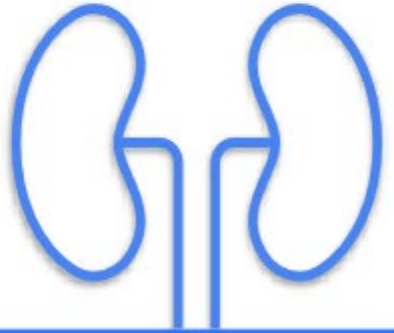
Hematologic disorders

Residents of nursing homes and other long-term care facilities

Neurologic disorders



Endocrine disorders such as diabetes



Kidney and liver disorders

Other underlying conditions or factors that the provider determines might increase the risk of severe respiratory illness

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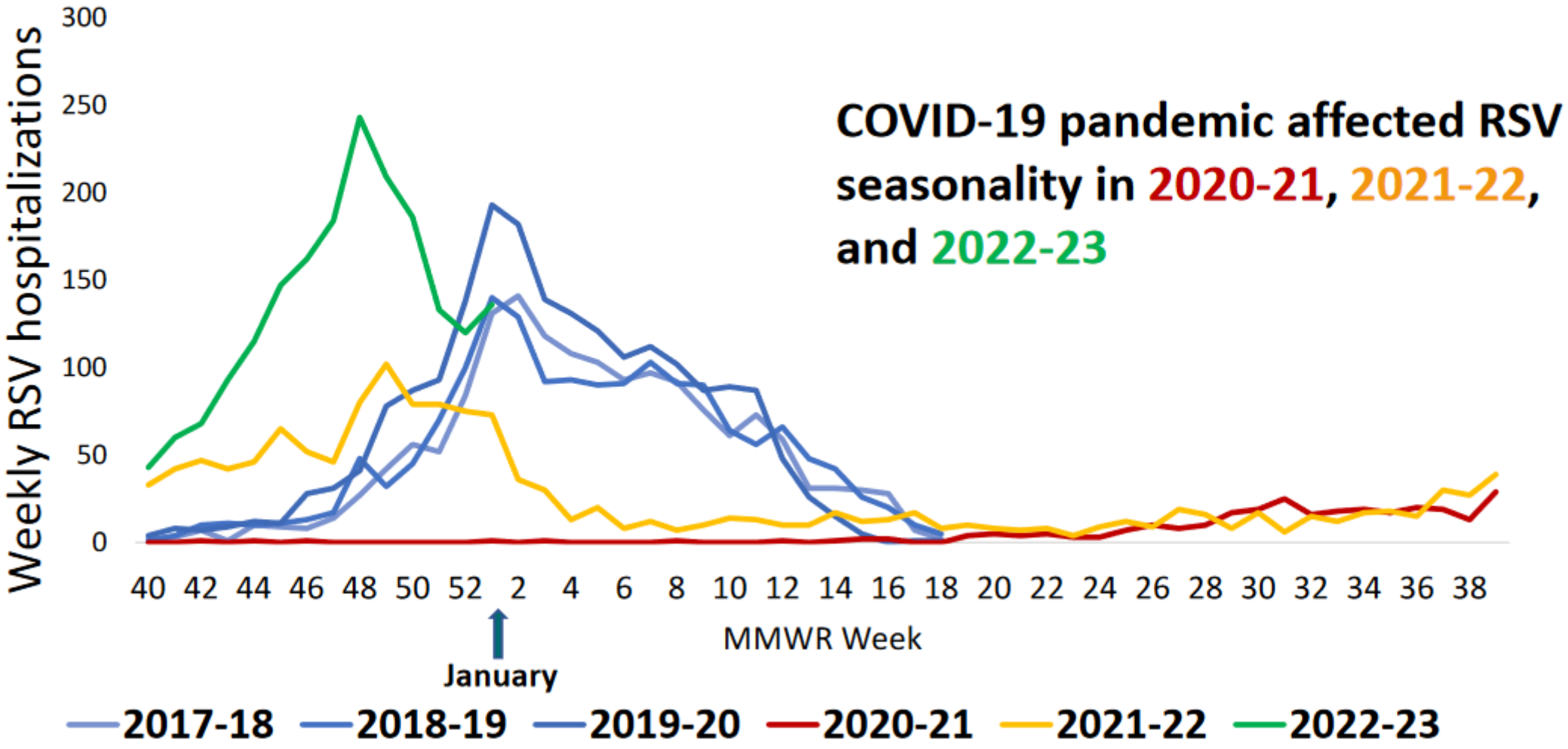
Clinical consideration: Timing of RSV vaccination for the 2023–2024 RSV season

RSV vaccination is currently approved and recommended as a single dose.

Optimally, vaccination of eligible adults should occur **before the onset of increased RSV activity** in the community.

The timing of the onset, peak, and decline of RSV activity varies each year, and RSV seasonality during the COVID-19 pandemic deviated from prior seasons.

RSV Hospitalizations in adults aged ≥65 years by season: RSV-NET 2017–2023



RSV-NET: unpublished data. Surveillance for 2017-18 through 2019-20 seasons were conducted from October – April; for 2020-21 and 2021-22 surveillance was conducted continuously from October – September. Data shown for 2022-23 season is from October – December 2022.

Clinical consideration: Timing of RSV vaccination for the 2023–2024 RSV season

Given this variability the ideal time to start vaccinating cannot be predicted in advance of the 2023-2024 RSV season.

Providers **should therefore offer RSV vaccination as soon as vaccine supply becomes available.**

Providers should continue to offer RSV vaccination throughout the RSV season to eligible adults who remain unvaccinated.

There are insufficient data at this time to determine the need for revaccination.

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Clinical consideration: Coadministration of RSV vaccines with other vaccines

In accordance with General Best Practice Guidelines for Immunization, coadministration of RSV vaccines with other adult vaccines is acceptable.*

This includes giving RSV vaccines simultaneously with seasonal influenza vaccines, COVID-19 vaccines, pneumococcal vaccines, Td/Tdap, and recombinant zoster vaccine (Shingrix).

*ACIP Timing and Spacing Guidelines for Immunization | CDC

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Reactogenicity and safety of coadministration of RSV vaccines with other vaccines

- Coadministration of multiple vaccines at the same visit may increase reactogenicity.
- Only coadministration of RSV and influenza vaccines have clinical trial data available. Evidence is mixed on whether there may be increased reactogenicity with coadministration of RSV and influenza vaccines.
- Data are lacking on coadministration of other vaccines that might be recommended for people in this age group, such as COVID-19 vaccines, pneumococcal vaccines, Td/Tdap, and the recombinant zoster vaccine (Shingrix by GSK) which contains the same adjuvant as RSVPreF3 vaccine (Arexvy by GSK).
- Post-licensure safety monitoring of coadministration of RSV vaccines with other vaccines will further inform coadministration guidance.

Clinical consideration: RSV vaccines and persons with immunocompromising conditions

Adults with immunocompromising conditions are at risk of severe RSV-associated disease and death.

They may benefit from RSV vaccination but were not included in the clinical trials so efficacy in this population is unknown.

These individuals, including those receiving immunosuppressive therapy, may have a diminished immune response to RSV vaccination.

Persons with immunocompromising conditions are recommended to receive the RSV vaccine under shared clinical decision-making given the potential for significant benefit.

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Vaccines Available

AREXVY
(RESPIRATORY SYNCYTIAL VIRUS VACCINE, ADJUVANTED)

https://www.abrysvo.com

https://arexvyhcp.com

RSV
Pediatric

- August 3, 2023, ACIP voted to recommend Nirsevimab for use in infants
- Infants aged <8 months born during or entering their first RSV reason are recommended to receive one dose of nirsevimab (50 mg for infants <5 kg and 100 mg for infants ≥5kg)
- Children aged 8-19 months who are at increased risk of severe RSV disease and entering their second RSV season are recommended to receive one dose of nirsevimab (200 mg)
- Approve the Vaccines for Children (VFC) resolution for nirsevimab for RSV.
- Per the manufacturer, the RSV season begins in November. As this monoclonal antibody as an effectiveness range of 5 months, it is recommended that vaccination will not occur until at least October

RSV
Pediatric

- VFC: CDC has determined that nirsevimab is eligible for inclusion in the childhood immunization schedule and Vaccines for Children program since there is no statutory definition of vaccine in the statute for VFC. Since nirsevimab will be included in VFC, practices must carry both VFC and private stock, which may be challenging for some practices. The VFC vaccine administration fee cap will apply to nirsevimab.
- Storage and Handling: Administered as an intramuscular injection with a single-dose, pre-filled syringe. Stored in the fridge at 2-8 degrees C and may be kept at room temperature for up to 8 hours.
- Dose by Weight/Age: 50 mg if <5kg, 100 mg if ≥5kg, 200 mg (2x100 mg) for high-risk children entering 2nd RSV season.
- Scope of Practice: CDC did a scan of different state statutes and laws looking at who is allowed to administer therapeutics. In most states, medical assistants who administer normal vaccines should be able to administer injectable drugs.
- Per the manufacturer, the RSV season begins in November. As this monoclonal antibody as an effectiveness range of 5 months, it is recommended that vaccination will not occur until at least October.

Flu Season 2023-2023

CDC estimates* that, from **October 1, 2022** through **April 30, 2023**, there have been:

27 – 54 million
flu **illnesses**

12 – 26 million
flu **medical visits**

300,000 – 650,000
flu **hospitalizations**

19,000 – 58,000
flu **deaths**

Flu in Southern Hemisphere

- Surveillance data show that several Southern Hemispheric countries are currently experiencing higher or earlier flu activity compared to what was seen prior to the COVID-19 pandemic; however, activity varies by country or region
- According to flu activity data submitted to the World Health Organization:
  - Influenza A(H1N1) viruses have been most commonly reported.
  - Chile has reported an early start to their flu season.
  - Argentina is experiencing typical levels of flu activity.
  - South Africa has been experiencing high flu activity for this time of year.
  - Australia is experiencing typical levels of flu activity.
  - While not in the Southern Hemisphere, Mexico has been experiencing abnormally high flu activity in May and June. Typically, Mexico has low flu activity during this time of the year.
    - https://www.cdc.gov/flu/spotlights/2022-2023/ongoing-flu-southern-hemisphere.htm

Flu Season 2023-2024

- There were small changes to the annual recommendations around flu vaccination,
  - updated flu vaccine composition for the 2023-2024 flu season
  - change in the recommendations for vaccination of people with egg allergies
- The 2023-2024 season U.S. flu vaccines will contain an updated influenza A(H1N1)pdm09 component:
  - A/Victoria/4897/2022 (H1N1)pdm09-like virus for egg-based vaccines and
  - A/Wisconsin/67/2022 (H1N1)pdm09-like virus for cell-based or recombinant vaccines.

Flu Vaccination and Egg Allergy

- The main change in the flu vaccine recommendations is related to giving flu vaccine to people with egg allergies.
  - Most flu vaccines today continue to be produced using an egg-based manufacturing process and therefore contain a small amount of egg proteins, such as ovalbumin.
  - While ACIP has *previous*ly recommended that all people 6 months and older with egg allergy should be vaccinated for flu, in the past there have been additional safety measures recommended for administration of egg-based flu vaccine to people who have had severe allergic reactions to egg.
  - The ACIP voted that people with egg-allergy may receive any flu vaccine (egg-based or non-egg based) that is otherwise appropriate for their age and health status.
  - Additional safety measures are no longer recommended for flu vaccination beyond those recommended for receipt of any vaccine.

Flu Vaccination Timing

- The recommended timing of flu vaccination has not changed.
  - September and October are the best times for most people to get vaccinated.
  - Flu vaccination in July and August is not recommended for most people, but there are several considerations regarding vaccination in July and August for specific groups of people:
    - For adults (especially those 65 years old and older) and pregnant people in the first and second trimester, vaccination in July and August should be avoided unless it won't be possible to vaccinate in September or October.
    - Pregnant people who are in their third trimester can get a flu vaccine in July or August in order to ensure their babies are protected from flu after birth, when they are too young to get vaccinated.
    - Children who need two doses of flu vaccine should get their first dose of vaccine as soon as vaccine becomes available. The second dose should be given at least four weeks after the first.
    - Vaccination in July or August can be considered for children who have health care visits during these months, if there might not be another opportunity to vaccinate them.
      - For example, some children might have medical visits in the late summer before school starts and might not return to see a health care provider in September or October.

Flu Vaccination for Children and Teems

Type Of Vaccine	Age Group	Dose	Route	Instructions §
Inactivated influenza vaccine (IIV4)	6–35 months	➢ Afluria: 0.25 mL ➢ Fluarix: 0.5 mL ➢ *Flucelvax: 0.5 mL (cell culture based)* FluLaval: 0.5 mL ➢ Fluzone: 0.25 or 0.5 ➢ mL	Intramuscular (IM)	Administer vaccine in anterolateral thigh muscle; alternatively, children age 12 through 35 months may re- ceive injection in deltoid muscle.
Inactivated influenza vaccine (IIV4) ➢ Afluria ➢ Fluarix ➢ *Flucelvax-cell cultured based* ➢ FluLaval ➢ Fluzone	3 years and older	0.5 mL	Intramuscular (IM)	Administer vaccine in deltoid muscle or, alternatively, in anterolateral thigh muscle.
Recombinant influenza vaccine (RIV4)-Flubloc	18 years and older	0.5 mL	Intramuscular (IM)	Administer vaccine in deltoid muscle.
Live attenuated influenza vaccine (LAIV4)-FluMist	Healthy, age 2 years and older (except if pregnant)	0.2 mL (0.1 mL into each nostril)	Intranasal spray (NAS)	Spray half of vaccine into each nostril while the patient is in an upright position.

Flu Vaccination for Adults

Type Of Vaccine	Vaccine Name	Adult Age Group	Dose	Route	Instructions‡
Inactivated influenza vaccine (IIV4)	➢ Afluria-Quad ➢ Flurix-Quad ➢ FluLaval-Quad ➢ Fluzone Quad	All adults	0.5 mL	Intramuscular (IM)	Administer vaccine in deltoid muscle.
IIV4-high dose *(preferred age 65+§)*	FluzoneHD-Quad	65 years and older	0.7 mL	Intramuscular (IM)	Administer vaccine in deltoid muscle.
Adjuvanted inactivated influenza vaccine¶(aIIV4) *(preferred age 65+§)*	Fluad-Quad	65 years and older	0.5 mL	Intramuscular (IM)	Administer vaccine in deltoid muscle.
Recombinant influenza vaccine (RIV4) *(preferred age 65+§)*	Flubloc-Quad	18 years and older	0.5 mL	Intramuscular (IM)	Administer vaccine in deltoid muscle.
Cell Culture-based IIV4 (ccIIV4)	Flucelvax-quad	All adults	0.5 mL	Intramuscular (IM)	Administer vaccine in deltoid muscle.
Live attenuated influenza vaccine (LAIV4)	FluMist	Healthy, younger than age 50 years (except if pregnant)	0.2 mL (0.1 mL into each nostril)	Intranasalspray (NAS)	Spray half of vaccine into each nostril while the patient is in an upright position.

Flu Vaccines Available

- For people younger than 65 years, CDC does not preferentially recommend any licensed, age-appropriate influenza (flu) vaccine over another. Options for this age group include inactivated influenza vaccine [IIV], recombinant influenza vaccine [RIV], or live attenuated influenza vaccine (LAIV).
- For people 65 years old and older, CDC and ACIP preferentially recommend the use of higher-dose flu vaccines (Fluzone High-Dose Quadrivalent inactivated influenza vaccine and Flublok Quadrivalent flu vaccine) or adjuvanted flu vaccine (Fluad Quadrivalent vaccine)

COVID-19 Vaccination

- FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) met on June 15, 2023, to discuss and make recommendations for SARS-CoV-2 strain(s) for updated COVID-19 vaccines for use in the United States beginning in the fall of 2023.
- For the 2023-2024 formulation of the COVID-19 vaccines for use in the U.S. beginning in the fall of 2023, the committee unanimously voted that the vaccine composition be updated to a monovalent COVID-19 vaccine with an XBB-lineage of the Omicron variant.
- Following discussion of the evidence, the committee expressed a preference for XBB.1.5.

Prevnar 20

- PREVNAR 20 is a vaccine approved for:
  - the prevention of invasive disease caused by 20 *Streptococcus pneumoniae* strains (1, 3, 4, 5, 6A, 6B, 7F, 8, 9V, 10A, 11A, 12F, 14, 15B, 18C, 19A, 19F, 22F, 23F, and 33F) in individuals 6 weeks and older.
  - the prevention of otitis media (middle ear infection) caused by 7 of the 20 strains in individuals 6 weeks through 5 years.

Prevnar 20
Adults

- All adults ≥65 years of age
- Adults aged 19 to 64 years with:
  - Predisposing chronic medical conditions (eg, chronic lung disease, chronic liver disease, diabetes mellitus)
  - Increased risk of meningitis (eg, cochlear implant, cerebrospinal fluid [CSF] leak)
  - Immunocompromising conditions (eg, human immunodeficiency virus [HIV] infection, hematologic malignancies) and other conditions associated with altered immunocompetence (functional or anatomic asplenia, chronic renal disease, and nephrotic syndrome)
  - Functional or anatomic asplenia

Vaccination Recommendations

- CDC recommends routine administration of pneumococcal conjugate vaccine (PCV15 or PCV20) for all adults 65 years or older who have never received any pneumococcal conjugate vaccine or whose previous vaccination history is unknown:
  - If PCV15 is used, this should be followed by a dose of PPSV23 one year later. The minimum interval is 8 weeks and can be considered in adults with an immunocompromising condition, cochlear implant, or cerebrospinal fluid leak.
  - If PCV20 is used, a dose of PPSV23 is NOT indicated.
    - See Pneumococcal Vaccination: Summary of Who and When to Vaccinate for CDC guidance on vaccination options for adults who have previously received a pneumococcal conjugate vaccine.

Prevnar 20
Pediatric

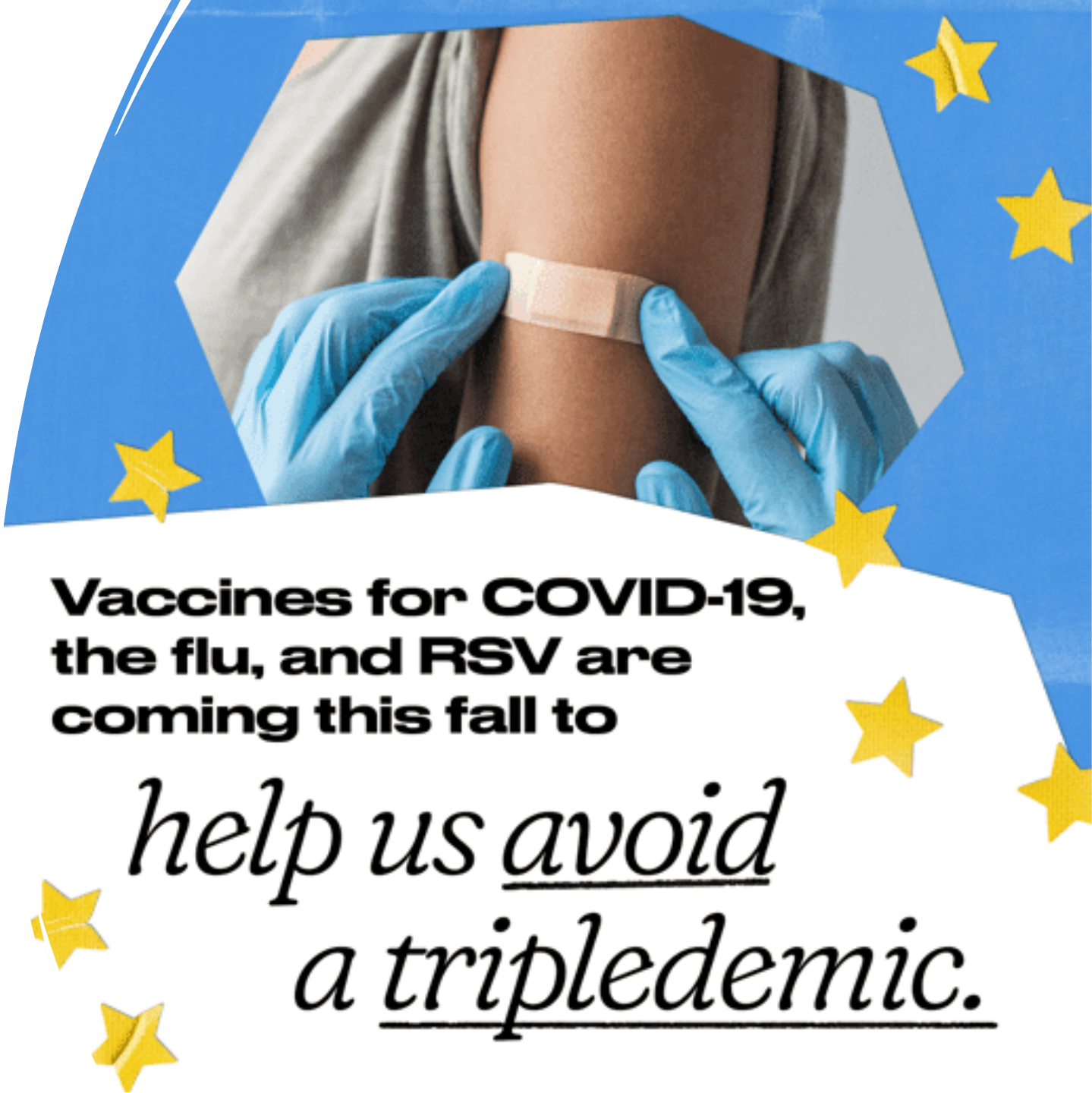
- Routine vaccination for all children under two years of age with a four-dose series at 2, 4, 6, and 12-15 months
- Vaccination for eligible children aged 2-18 years with certain underlying medical conditions that increase their risk for pneumococcal disease
- A catch-up dose for children with an incomplete PCV vaccination status for:
  - healthy children aged 24-59 months
  - children aged 24-71 months with certain underlying medical conditions that increase their risk for pneumococcal disease

ACIP Recommendations

- Use of either pneumococcal conjugate vaccines (PCV) PCV15 or PCV20 is recommended for all children aged 2–23 months according to currently recommended PCV dosing and schedules.
- For children with an incomplete PCV vaccination status, use of either PCV15 or PCV20 according to currently recommended PCV dosing and schedules is recommended for:
  - Healthy children aged 24–59 months
  - Children with specified health conditions(2) aged 24 through 71 months
- For children aged 2–18 years with any risk condition who have received all recommended doses of PCV before age 6 years
  - Using ≥1 dose(s) of PCV20: No additional doses of any pneumococcal vaccine are indicated. This recommendation may be updated as additional data become available.
  - Using PCV13 or PCV15 (no PCV20): A dose of PCV20 or PPSV23 using previously recommended dosing and schedules is recommended.
- For children aged 6–18 years with any risk condition who have not received any dose of PCV13, PCV15, or PCV20, a single dose of PCV15 or PCV20 is recommended. When PCV15 is used, it should be followed by a dose of PPSV23 at least 8 weeks later if not previously given
    - *Per ACIP, either PCV15 or PCV20 may be used for the full series or to complete the recommended schedule begun with PCV13*
      - *If you only have PCV13 this may be given as previously recommended*

Teaching Opportunity

- *The vaccines discussed in this presentation may be administered at the same visit.*
- *For those patients with Medicare Part D, The Inflation Reduction Act improved coverage for these vaccines.*
- *$0 out of pocket*
- *A strong recommendation from a trusted healthcare team is needed to improve vaccination and decrease mortality and morbidity.*



Meningococcal Vaccines

- Menveo by GSK is now supplied in two presentations
  - Menveo Two-Vial* presentation (existing presentation-requires reconstitution) approved for ages 2 months through 55 years
  - **Menveo One-Vial presentation** (**new presentation- does not require reconstitution)** approved for use in **ages 10 through 55 years**

- Other MenACWY vaccines available for young children – (existing vaccines)
  - Menactra - licensed for 9 months through 55 years (discontinued this summer)
  - MenQuadfi - licensed for 2 years and older

**GSK plans to maintain a consistent but limited supply of Menveo Two-Vial for children <10 years*